



Billing Code 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Draft NTP Technical Reports on Prenatal Developmental Toxicity Studies; Availability of Documents; Request for Comments; Notice of Peer-Review Meeting

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Toxicology Program (NTP) announces the availability of four draft NTP Technical Reports on prenatal developmental toxicity studies scheduled for peer-review for the following substances: tris(chloropropyl) phosphate, 4-methylcyclohexanemethanol, vinpocetine, and dimethylaminoethanol bitartrate. The peer-review meeting is open to the public. Registration is required for in-person meeting attendance, oral comment, and to access the webcast. Information about the meeting and registration is available at <https://ntp.niehs.nih.gov/go/36051>.

DATES:

Meeting: July 31, 2019, 8:30 a.m. to adjournment at approximately 5:00 p.m. Eastern Daylight Time (EDT). The meeting may end earlier or later than 5:00 p.m. EDT.

Document Availability: The four draft NTP Technical Reports should be available by June 5, 2019, at <https://ntp.niehs.nih.gov/go/36051>.

Written Public Comment Submissions: Deadline is July 17, 2019.

Registration for Oral Comments: Deadline is July 17, 2019.

Registration to Attend Meeting In-Person: Deadline is July 17, 2019.

Registration to View Webcast: Deadline is July 31, 2019.

ADDRESSES:

Meeting Location: Conference Room F193, Rall Building, NIEHS, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709.

Meeting Web page: The draft reports, preliminary agenda, registration, and other meeting materials will be available at <https://ntp.niehs.nih.gov/go/36051>.

Webcast: The URL for viewing the peer-review meeting webcast will be provided to registrants.

FOR FURTHER INFORMATION CONTACT: Email NTP-Meetings@icf.com. Dr.

Elizabeth Maull, NIEHS/DNTP, is the Designated Federal Official. Phone: (984) 287-3157,

Fax: (301) 480-3008. Email: maull@niehs.nih.gov.

SUPPLEMENTARY INFORMATION:

Meeting Attendance Registration: The meeting is open to the public with time set aside for oral public comment. As meeting space at NIEHS is under renovation, very limited space is available for in-person attendance (~15 attendees). Registration for in-person attendance is on a first-come, first-served basis. After maximum capacity is reached, persons will be placed on a

wait list and notified should an opening become available. Registration to attend the meeting in person is by July 17, 2019, at <https://ntp.niehs.nih.gov/go/36051> and for the webcast is July 31, 2019, at <https://ntp.niehs.nih.gov/go/36051>. The URL for the webcast will be provided in the email confirming registration. Visitor and security information for those attending in person is available at <https://www.niehs.nih.gov/about/visiting/index.cfm>. Individuals with disabilities who need accommodation to view the webcast should contact Susan Blaine by phone: (703) 225-2471 or email: NTP-Meetings@icf.com. TTY users should contact the Federal TTY Relay Service at (800) 877-8339. Requests should be made at least five business days in advance of the event.

Request for Comments: NTP invites written and oral public comments on the draft reports that address scientific or technical issues. Guidelines for public comments are at https://ntp.niehs.nih.gov/ntp/about_ntp/guidelines_public_comments_508.pdf.

The deadline for submission of written comments is July 17, 2019, to enable review by the peer-review panel and NTP staff prior to the meeting. Written public comments should be submitted through the meeting website at <https://ntp.niehs.nih.gov/go/36051>. Persons submitting written comments should include name, affiliation, mailing address, phone, email, and sponsoring organization (if any). Written comments received in response to this notice will be posted on the NTP website and the submitter will be identified by name, affiliation, and sponsoring organization (if any). Comments that address scientific or technical issues will be forwarded to the peer-review panel and NTP staff prior to the meeting.

Oral public comment at this meeting is welcome, with time set aside for the presentation of oral comments on the draft reports. The agenda allows for four public comment periods – one

comment period per report (up to 6 commenters, up to 5 minutes per speaker, per report).

Persons wishing to make an oral comment are required to register online at <https://ntp.niehs.nih.gov/go/36051> by July 17, 2019, and indicate whether they will present comments in-person or via the teleconference line. Registration is on a first-come, first served basis. Each organization is allowed one time slot per report. The access number for the teleconference line will be provided to registrants by email prior to the meeting. Commenters will be notified approximately one week before the peer-review meeting about the actual time allotted per speaker.

If possible, oral public commenters should send a copy of their slides and/or statement or talking points to Susan Blaine by email: NTP-Meetings@icf.com by July 17, 2019. Written statements can supplement and may expand the oral presentation.

Meeting Materials: The draft NTP technical reports and preliminary agenda will be available on the NTP website at <https://ntp.niehs.nih.gov/go/36051> prior to the meeting. NTP expects that the draft reports should be available on the website by June 5, 2019. Additional information will be posted when available or may be requested in hardcopy from Susan Blaine by phone: (703) 225-2471 or email: NTP-Meetings@icf.com. Individuals are encouraged to access the meeting web page to stay abreast of current information regarding the meeting.

Following the meeting, a report of the peer-review will be prepared and made available on the NTP website.

Background Information on NTP Peer-Review Panels: NTP panels are technical, scientific advisory bodies established on an “as needed” basis to provide independent scientific

peer-review and advise NTP on agents of public health concern, new/revised toxicological test methods, or other issues. These panels help ensure transparent, unbiased, and scientifically rigorous input to the program for its use in making credible decisions about human hazard, setting research and testing priorities, and providing information to regulatory agencies about alternative methods for toxicity screening. NTP welcomes nominations of scientific experts for upcoming panels. Scientists interested in serving on an NTP panel should provide their current curriculum vitae to Susan Blaine by email: NTP-Meetings@icf.com.

The authority for NTP panels is provided by 42 U.S.C. 217a; section 222 of the Public Health Service Act, as amended. The panel is governed by the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

This peer review is being conducted by a panel in attendance at NIEHS. Peer-review of future draft reports will be conducted in accordance with Department of Health and Human Services peer-review policies (<https://aspe.hhs.gov/hhs-information-quality-peer-review>) and Office of Management and Budget's Final Information Quality Bulletin for Peer Review (70 FR 2664, January 4, 2005).

Dated: May 21, 2019.

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National Toxicology Program.

[FR Doc. 2019-11463 Filed: 5/31/2019 8:45 am; Publication Date: 6/3/2019]